DePuy
a Johnson & Johnson company

K010171

510(k) SUMMARY

NAME OF FIRM:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(K) CONTACT:	Arlene C. Saull, RAC Sr. Regulatory Associate DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581-0988
TRADE NAME:	Duraloc® Acetabular Cup System, 36mm Marathon™ +4 Polyethylene Liner
COMMON NAME:	Acetabular Cup Liner
CLASSIFICATION:	Class II, per 21 CFR, 888.3358
DEVICE PRODUCT CODE:	87 LPH: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented.
SUBSTANTIALLY EQUIVALENT DEVICES:	**DePuy** Duraloc® Acetabular Cup Liners **DePuy** Marathon™ Cross-Linked Polyethylene Acetabular Cup Liners **Sulzer** Inter-Op™ Acetabular Inserts and CoCr Femoral Heads (in four sizes 28mm to 46mm)

DEVICE DESCRIPTION:

The subject Marathon liners are UHMWPe acetabular cup liners that are available with a 36mm inner diameter and are lateralized 4mm. The subject Marathon liners are available in a neutral orientation and with a 10° lip. They are geometrically identical to other Duraloc Acetabular Cup Liners with the exception of having a larger (36mm) inner diameter intended for use with 36mm femoral heads.

INDICATIONS AND INTENDED USE:

Intended Use:

The subject 36mm Marathon Cross-Linked +4 Polyethylene Liners are intended to be used with the DePuy Duraloc metal acetabular shells to resurface the acetabular socket in cemented or cementless total hip arthroplasty.

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Indications:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.

2. Avascular necrosis of the femoral head.

3. Acute traumatic fracture of the femoral head or neck

4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

5. Certain cases of ankylosis.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The *subject* devices have the following similarities to the *predicate* DePuy polyethylene liners that were cleared in K972596 and K994415:

- Same intended use
- Same indications
- Same cross-linked polyethylene
- Same method of manufacture
- Same design
- Same mating components
- Same sterilization and packaging methods

The *subject* devices have the following similarities to the *predicate* Sulzer polyethylene liners that were cleared in submission, K993259:

- Similar intended use
- Similar indications
- Similar cross-linked polyethylene material
- Similar design
- The 36mm subject DePuy Marathon liner falls within the size range of the predicate Sulzer liners, cleared in 28mm, 32mm, 38mm and 46mm inner diameters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 2001

Ms. Arlene C. Saull, RAC
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581-0988

Re: K010171
Trade Name: 36mm Marathon™ +4 Polyethylene Liners
Regulatory Class: II
Product Code: LPH
Dated: January 17, 2001
Received: January 18, 2001

Dear Ms. Saull:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS

510(k) Premarket Notification

510(k) Number (if known) K010171

Device Name: Duraloc® Acetabular Cup System – 36mm Marathon™ +4 Polyethylene Liners

Indications for Use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Concurrence of CDRH, Office of Device Evaluation:

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010171

Prescription Use X or Over-The-Counter Use ___ (Per 21 CFR 801.109)